

ORIGINAL ARTICLE

Wound classification reporting in HPB surgery: can a single word change public perception of institutional performance?

Paul J. Speicher, Daniel P. Nussbaum, John E. Scarborough, Sabino Zani, Rebekah R. White, Dan G. Blazer III, Christopher R. Mantyh, Douglas S. Tyler & Bryan M. Clary

Department of Surgery, Duke University Medical Center, Durham, NC, USA

Abstract

Introduction: The drive to improve outcomes and the inevitability of mandated public reporting necessitate uniform documentation and accurate databases. The reporting of wound classification in patients undergoing hepato-pancreatico-biliary (HPB) surgery and the impact of inconsistencies on quality metrics were investigated.

Methods: The 2005–2011 National Surgical Quality Improvement Program (NSQIP) participant use file was interrogated to identify patients undergoing HPB resections. The effect of wound classification on post-operative surgical site infection (SSI) rates was determined through logistic regression. The impact of variations in wound classification reporting on perceived outcomes was modelled by simulating observed-to-expected (O/E) ratios for SSI.

Results: In total, 27 376 patients were identified with significant heterogeneity in wound classification. In spite of clear guidelines prompting at least ‘clean-contaminated’ designation for HPB resections, 8% of all cases were coded as ‘clean’. Contaminated [adjusted odds ratio (AOR): 1.39, $P = 0.001$] and dirty (AOR: 1.42, $P = 0.02$) cases were associated with higher odds of SSI, whereas clean-contaminated were not ($P = 0.99$). O/E ratios were highly sensitive to modest changes in wound classification.

Conclusions: Perceived performance is affected by heterogeneous reporting of wound classification. As institutions work to improve outcomes and prepare for public reporting, it is imperative that all adhere to consistent reporting practices to provide accurate and reproducible outcomes.

Received 5 March 2014; accepted 2 April 2014

Correspondence

Bryan M. Clary, Duke University Medical Center, 485 Seeley G. Mudd Building, Durham, NC 27710, USA.
Tel: 919 684 6553. Fax: 919 681 7508. E-mail: bryan.clary@duke.edu

Introduction

Recent initiatives to improve surgical outcomes, including the National Surgical Quality Improvement Program (NSQIP), have emphasized the need to standardize the reporting of quality metrics nationwide. It is generally accepted that, in addition to being used as a tool to compare surgeons and institutions, similar metrics will also become publicly available information in the near future. To ensure that patients have access to the most accurate clinical outcomes and that providers are receiving high-quality feedback, it is essential that

comparisons be made using a common language and consistent benchmarks.

Surgical site infection (SSI) represents a major source of morbidity for patients undergoing hepato-pancreatico-biliary (HPB) procedures. Historically, surgical wound classification has been thought to be predictive of SSI rates; however, this has not been well studied in the modern HPB era. While rates of SSI after major HPB procedures have been described, there is a paucity of literature regarding the current reporting of wound classification as it relates to SSI rates and the inherent implications for quality reporting and improvement.^{1–5}

The primary objective of this study was to use a national clinical database to examine the current status of wound classification reporting and the effect on subsequent SSI rates for four major

This study was presented at the Annual Meeting of the AHPBA, 19–23 February 2014, Miami, Florida.

Table 1 Surgical wound classifications

Class I/Clean: An uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tract is not entered. In addition, clean wounds are primarily closed and, if necessary, drained with closed drainage. Operative incisional wounds that follow non-penetrating (blunt) trauma should be included in this category if they meet the criteria.

Class II/Clean-Contaminated: An operative wound in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled conditions and without unusual contamination. Specifically, operations involving the biliary tract, appendix, vagina and oropharynx are included in this category, provided no evidence of infection or major break in technique is encountered.

Class III/Contaminated: Open, fresh, accidental wounds. In addition, operation with major breaks in sterile technique or gross spillage from the gastrointestinal tract, and incisions in which acute, non-purulent inflammation is encountered are included in this category.

Class IV/Dirty-Infected: Old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing post-operative infection were present in the operative field before the operation.

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types of HPB procedures. Secondarily, we sought to examine how variations in wound classification reporting can influence perceived outcomes and performance in the form of observed-to-expected (O/E) ratios.

Methods

The NSQIP Participant User Files (PUF) from 2005 through to 2011 were used for this analysis, looking at four *a priori* defined groups of procedures: isolated liver resection, liver resection with a concomitant biliary or small bowel procedure, distal pancreatectomy and pancreaticoduodenectomy. All patients with a primary Current Procedural Terminology (CPT) code for liver resection (47120, 47122, 47125 and 47130), distal pancreatectomy (48140, 48145 and 48146), or pancreaticoduodenectomy (48150 and 48152-4) were included in the analysis. Liver resection cases were further stratified into those with an associated CPT code for concomitant biliary or bowel procedure, and those without. To capture only non-emergent cases, emergency cases and cases identified as American Society of Anesthesiology (ASA) class 5, defined as a moribund patient who is not expected to survive without the operation, were excluded from analysis. The primary outcome measure for the analysis was the rate of post-operative SSI, defined as either superficial, deep, or organ-space infection occurring within 30 days of the operation and which appeared to be related to the procedure. Wound classifications, as defined by the World Health Organization, are outlined in Table 1. Rates of SSI were subsequently stratified by wound classification and procedure type.

For continuous and categorical variables, measures of central tendency and proportions were assessed, respectively. Pre-operative baseline patient characteristics were compared for patients undergoing the four pre-defined HPB procedure groups using Pearson's chi-square test for categorical variables and one-way ANOVA for continuous variables. Univariate comparisons of wound classification by procedure type were performed using Pearson's chi-square tests, as were comparisons of SSI rates stratified by wound classification for each procedure.

To determine the independent effect of wound classification status on rates of post-operative SSI, a stepwise forward multiple

logistic regression model consistent with previously reported traditional NSQIP risk-adjustment was created.^{7–10} In addition to wound classification, the following predictor variables were considered for inclusion in this risk-adjustment model: procedure type (liver resection, liver resection with concomitant biliary/bowel procedure, distal pancreatectomy and pancreaticoduodenectomy), patient age, gender, body mass index, ASA classification, tobacco use within the past year, >2 alcoholic drinks per day, dyspnoea at rest or on exertion, diabetes mellitus, chronic obstructive pulmonary disease, hypertension, coronary artery disease (angina, history of myocardial infarction, percutaneous coronary intervention, or coronary artery bypass graft procedure), congestive heart failure, peripheral vascular disease (revascularization procedure, claudication, rest pain, gangrene and amputation), pre-operative dependence on dialysis, existing neurological disease (stroke, TIA, impaired sensation, hemiplegia, paraplegia, or quadriplegia), ascites, pre-operative diagnosis of pneumonia, the use of steroids within 30 days of operation for a chronic medical condition, systemic chemotherapy within 30 days of operation, radiotherapy treatment for cancer in the 90 days prior to surgery, >10% loss of body weight in 6 months prior to operation, bleeding disorder and the need for a pre-operative packed red blood cell transfusion. Pre-operative laboratory values included in the model were serum sodium, albumin, blood urea nitrogen, creatinine, haematocrit, platelet count, white blood cell count, partial thromboplastin time and prothrombin time.

To model the effect of variation in wound classification reporting, three 'hypothetical' institutions were created: (i) average performance with baseline O/E ratio of 1.0; (ii) poor performance with baseline O/E ratio of 1.5; and (iii) superior performance with baseline O/E ratio of 0.67. For each of these institutions, the hypothetical O/E ratio was based on observed rates of SSI and the actual distribution of wound classification reporting in our study cohort. To quantify the effect of changes wound classification reporting on expected rates of SSI for these hypothetical institutions, the proportion of cases reported as 'Contaminated' and 'Clean-contaminated' were varied while holding the percentage of 'Clean' and 'Dirty' cases constant. Corresponding changes in expected SSI rates were calculated based on the previously developed risk-adjustment model. By taking the ratios of the baseline

Table 2 Pre- and intra-operative characteristics

| Characteristic | Procedure | | | | | P-value |
|---------------------------------------|-----------------------|--------------------------------------|---|--|--|---------|
| | Total (n = 27 376) | Liver resection, alone (n = 9128) | Liver resection, with other procedure (n = 1047) | Distal pancreatectomy (n = 5608) | Pancreatico- duodenectomy (n = 11 593) | |
| Age (median, years) | 62 | 60 (50,68) | 62 (53,69) | 60 (50,70) | 65 (56,73) | <0.001 |
| Female gender | 14091 | 4735 (52%) | 507 (48.5%) | 3221 (57.5%) | 5628 (48.6%) | <0.001 |
| Tobacco smoker | 5354 | 1483 (16.2%) | 166 (15.9%) | 1203 (21.5%) | 2502 (21.6%) | <0.001 |
| Preoperative dyspnoea | 2349 | 792 (8.7%) | 91 (8.7%) | 502 (9%) | 964 (8.3%) | 0.542 |
| Do-not-resuscitate order | 46 | 10 (0.1%) | 2 (0.2%) | 11 (0.2%) | 23 (0.2%) | 0.320 |
| Diabetes mellitus | 5479 | 1497 (16.4%) | 138 (13.2%) | 1175 (21%) | 2669 (23%) | <0.001 |
| Chronic steroid use | 540 | 180 (2%) | 16 (1.5%) | 130 (2.3%) | 214 (1.8%) | 0.139 |
| Non-independent functional status | 563 | 128 (1.4%) | 28 (2.7%) | 121 (2.2%) | 286 (2.5%) | <0.001 |
| Alcohol >2 drinks/day | 686 | 211 (2.6%) | 27 (3%) | 122 (2.5%) | 326 (3.2%) | 0.019 |
| COPD | 1075 | 275 (3%) | 34 (3.2%) | 260 (4.6%) | 506 (4.4%) | <0.001 |
| Coronary artery disease | 2221 | 592 (7.3%) | 64 (7%) | 459 (9.3%) | 1106 (11%) | <0.001 |
| Congestive heart failure | 64 | 18 (0.2%) | 2 (0.2%) | 12 (0.2%) | 32 (0.3%) | 0.707 |
| Pre-operative dialysis | 101 | 35 (0.4%) | 3 (0.3%) | 25 (0.4%) | 38 (0.3%) | 0.659 |
| Disseminated cancer | 4494 | 3578 (39.2%) | 345 (33%) | 280 (5%) | 291 (2.5%) | <0.001 |
| INR | 1.0 | 1.0 (1,1.1) | 1.0 (1,1.1) | 1.0 (1,1.1) | 1.0 (1,1.1) | <0.001 |
| Bilirubin | 0.6 | 0.6 (0.4,0.8) | 0.7 (0.4,1.11) | 0.5 (0.4,0.7) | 0.8 (0.5,2.1) | <0.001 |
| AST | 27 | 27 (21,39) | 30 (22,52) | 22 (18,28) | 31 (22,65) | <0.001 |
| Alkaline phosphatase | 96 | 90 (70,121) | 113 (78,215) | 78 (62,98) | 124 (80,250) | <0.001 |
| Albumin | 3.9 | 4.1 (3.7,4.4) | 3.9 (3.4,4.2) | 4 (3.7,4.4) | 3.8 (3.3,4.2) | <0.001 |
| >10% weight loss in past 6 months | 3138 | 411 (4.5%) | 108 (10.3%) | 501 (8.9%) | 2118 (18.3%) | <0.001 |
| Bleeding disorder | 806 | 317 (3.5%) | 33 (3.2%) | 176 (3.1%) | 280 (2.4%) | <0.001 |
| Pre-operative transfusion requirement | 145 | 31 (0.3%) | 8 (0.8%) | 37 (0.7%) | 69 (0.6%) | 0.018 |
| Chemotherapy within 30 days | 1104 | 704 (8.7%) | 64 (7%) | 77 (1.6%) | 259 (2.6%) | <0.001 |
| Radiation therapy within 90 days | 467 | 84 (1%) | 19 (2.1%) | 62 (1.3%) | 302 (3%) | <0.001 |
| SIRS | 425 | 114 (1.2%) | 27 (2.6%) | 79 (1.4%) | 205 (1.8%) | 0.001 |
| Sepsis | 558 | 141 (1.6%) | 38 (3.7%) | 111 (2%) | 268 (2.3%) | <0.001 |
| Septic Shock | 12 | 5 (0.1%) | 2 (0.2%) | 3 (0.1%) | 2 (0.0%) | 0.062 |
| ASA Class 3 or greater | 18383 | 6186 (67.8%) | 734 (70.1%) | 3369 (60.1%) | 8094 (69.8%) | <0.001 |
| Operative time (median, min) | 277 | 212 (151,288) | 324 (238,451.5) | 210 (157,283) | 357 (285,443) | <0.001 |

COPD, chronic obstructive pulmonary disease; INR, International Normalized Ratio; AST, aspartate transaminase; SIRS, systemic inflammatory response syndrome; ASA, American Society of Anesthesiologists.

observed SSI rates to these newly simulated expected SSI rates, the overall impact on O/E ratio was estimated for each of the three previously defined hypothetical institutions as a function of wound classification.

Consistent with previous studies modelling NSQIP data, laboratory values were categorized as normal or abnormal using standard cutoffs, and missing data were assigned a third categorical indicator variable. Missing data for variables other than laboratory values were handled with complete case analysis, given the substantial completeness of NSQIP data for variables other than laboratory values. Model diagnostics and balance were assessed, and no major model assumptions were violated. A P -value ≤ 0.05 was used to

indicate statistical significance for all comparisons and analyses. Statistical analyses were performed using R version 3.0.1 (The R Foundation for Statistical Computing, Vienna, Austria).

Results

A total of 27 376 cases were identified which met study inclusion criteria. Of these, there were 9128 (33.3%) isolated liver resections, 1047 (3.8%) liver resections with concomitant biliary or bowel procedures, 5608 (20.5%) distal pancreatectomies and 11 593 (42.3%) pancreaticoduodenectomies. Baseline patient characteristics stratified by procedure type are shown in Table 2.

Table 3 Surgical wound classifications, and subsequent rates of surgical site infection, stratified by surgical procedure

| | Liver resection, alone (n = 9128) | Liver resection, with other procedure (n = 1047) | Distal pancreatectomy (n = 5608) | Pancreatico- duodenectomy (n = 11 593) | P-value |
|--|--------------------------------------|---|--|--|---------|
| Wound classification breakdown | | | | | |
| Clean | 1566 (17.2%) | 54 (5.2%) | 440 (7.8%) | 103 (0.9%) | <0.001 |
| Clean/Contaminated | 7057 (77.3%) | 851 (81.3%) | 4710 (84.0%) | 10270 (88.6%) | |
| Contaminated | 401 (4.4%) | 104 (9.9%) | 352 (6.3%) | 1015 (8.8%) | |
| Dirty/Infected | 104 (1.1%) | 38 (3.6%) | 106 (1.9%) | 205 (1.8%) | |
| Subsequent SSI rates, by wound classification | | | | | |
| Clean | 9.6% | 31.5% | 13% | 15.5% | <0.001 |
| Clean/Contaminated | 8.5% | 25.5% | 14.2% | 21.2% | <0.001 |
| Contaminated | 17.2% | 37.5% | 19.9% | 26.7% | <0.001 |
| Dirty/Infected | 16.3% | 28.9% | 20.8% | 30.2% | 0.036 |

SSI, surgical site infection.

Table 4 Multivariable logistic regression for risk of surgical site infection (SSI) by surgical wound classification

| Wound classification | Odds ratio | 95% Confidence interval | | P-value | Expected SSI rate | 95% Confidence interval | |
|----------------------|------------|-------------------------|-------|---------|-------------------|-------------------------|-------|
| | | Lower | Upper | | | Lower | Upper |
| Clean | Ref | Ref | Ref | Ref | 18.9% | 16.2% | 21.9% |
| Clean/Contaminated | 1.00 | 0.86 | 1.17 | 0.999 | 19.0% | 17.3% | 20.4% |
| Contaminated | 1.39 | 1.14 | 1.69 | 0.001 | 24.6% | 21.8% | 27.4% |
| Dirty/Infected | 1.42 | 1.06 | 1.91 | 0.019 | 25.2% | 20.2% | 30.3% |

The distribution of wound classification reporting, stratified by procedure type, is shown in Table 3. There was significant variation between groups ($P < 0.001$), but the large majority of cases for all HPB procedures were coded as clean-contaminated (77.3% of isolated liver resections, 81.3% of liver resections with concomitant biliary/bowel procedures, 84.0% of distal pancreatectomies and 88.6% of pancreaticoduodenectomies). Of note, 5.2% of liver resections with concomitant biliary/bowel procedures and 0.9% of pancreaticoduodenectomies were classified as clean, presumably incorrectly.

Rates of SSI, stratified by procedure type and wound classification, are also shown in Table 3. Comparing across procedures with respect to specific wound classifications, SSI rates were highly variable (clean: $P < 0.001$, clean-contaminated: $P < 0.001$, contaminated: $P < 0.001$, dirty: $P = 0.04$). SSI rates for clean and clean-contaminated cases were very similar to one another, but SSI rates were consistently higher for contaminated and dirty cases. After adjustment with multivariable logistic regression, compared with clean cases, clean-contaminated cases were not associated with significantly higher odds of SSI (AOR 1.0, $P = 0.99$). Contaminated (AOR 1.39, $P = 0.001$) and dirty (AOR 1.42, $P = 0.02$) cases, however, were associated with significantly higher odds of SSI. Expected rates of SSI for HPB procedures, based on our risk-adjustment model and stratified by wound classification, are outlined in Table 4.

The effects of simulated changes in wound classification on hypothetical O/E ratios are shown in Table 5. Increasing percentages of cases coded as contaminated (versus clean-contaminated) were associated with concomitant decreases in O/E ratios for all three hypothetical institutions, resulting in improved perceived performance. By increasing the percentage of cases coded as contaminated from a baseline of 6.8% up to 50%, O/E ratios improved 11%, from 1.0 to 0.92, from 1.5 to 1.39, and from 0.67 to 0.62, for the three hypothetical situations, respectively.

Discussion

In this analysis, we report on the relationship between wound classification and the rate of SSI, demonstrate inconsistencies in wound classification reporting nationally and have modelled the impact of these inconsistencies on subsequent perceived performance. It has been shown that wound classifications inadequately predict SSI rates as they are currently used in HPB surgery, and that minor changes in wound classification reporting policies can have significant influence on quality metrics.

Interestingly, we found that approximately 1% of pancreaticoduodenectomies and 5% of liver resections involving a concomitant biliary or bowel procedure were coded as 'clean' cases in NSQIP. Given that all procedures where the bowel is transected warrant a classification of at least clean-contaminated, the coding

Table 5 Simulated change in O/E ratios based on per cent of cases coded as contaminated, for various baseline performance

| Per cent cases coded as contaminated (versus clean-contaminated) | Hypothetical baseline O/E performance | | | Percent change in O/E ratio |
|--|---------------------------------------|--------------------------|-----------------------|-----------------------------|
| | High performer 0.67 | Average performer 1.0 | Poor performer 1.5 | |
| 0% | 0.69 | 1.03 | 1.54 | 2.1% |
| 6.8% (baseline) | 0.67 | 1.00 | 1.50 | 0.0% |
| 10% | 0.66 | 0.99 | 1.48 | -0.8% |
| 20% | 0.65 | 0.97 | 1.46 | -3.6% |
| 30% | 0.64 | 0.96 | 1.43 | -6.2% |
| 40% | 0.63 | 0.94 | 1.41 | -8.6% |
| 50% | 0.62 | 0.92 | 1.39 | -11.0% |
| 60% | 0.61 | 0.91 | 1.36 | -13.2% |
| 70% | 0.60 | 0.90 | 1.34 | -15.3% |

Modelled based on observed rates of SSI and wound classification reporting for HPB cases in NSQIP; changes in O/E ratio reflect approximate changes predicted using traditional NSQIP logistic regression risk-adjustment model.

SSI, surgical site infection; O/E ratio, observed-to-expected ratio.

of these cases is difficult to understand or explain, and likely represents either misinterpretation of the classification criteria or incorrect data entry. In either case, this is certainly an area for future quality improvement. Along similar lines, cases recorded as 'clean' and 'clean-contaminated' were found to have similar rates of SSI across all HPB procedures, suggesting that as currently utilized there may be no functional distinction between these classifications in our study cohort with regard to SSI. Alternatively, cases classified as contaminated or dirty/infected were associated with significantly higher SSI rates, as would be expected.

The risk of surgical site infections has traditionally been associated with wound classification. Historically, estimates of SSI rates for clean cases ranged from 1–5%, for clean-contaminated 3–11%, contaminated 10–17% and dirty/infected >27%.¹¹ Based on conventional wound classification schemes, major HPB procedures would rarely if ever qualify as truly 'clean' cases, although there remains some debate regarding whether transecting only the liver parenchyma or distal pancreatic duct should technically be considered a violation of the alimentary tract. Doing so, however, nonetheless violates a potentially non-sterile viscus in continuity with the gastrointestinal tract, and such cases should be considered clean-contaminated. More obviously, for operations requiring entry into the extrahepatic biliary tree or small bowel, a classification of clean is clearly inappropriate. The microbiology profile of bile has been well documented, and many patients undergoing major HPB procedures either have known biliary pathology (e.g. strictures, stones, or other obstruction) or have had previous instrumentation of the biliary tree and possible stent placement, which constitute known risk factors for bactibilia.^{12–15} Pre-operative biliary drainage continues to play a major role in the management of this patient population, and studies suggest that 74–83% of these patients will have positive bile cultures, probably related to the foreign-body stent present in the biliary tree.^{16,17} Because of this, the implications of continuous bile spillage during

lengthy HPB operations takes on added importance. Such bile should be considered non-sterile if not frankly infected, and classifying such cases as contaminated warrants serious consideration.

In addition to being a major source of morbidity after HPB procedures, SSI is also an important measure of quality. As clinical decisions and patient choices become increasingly tied to available performance and outcomes data, the impact of how clinical care information is collected and documented is of paramount importance. Accuracy and consistency in reporting are essential, and although here we present a hypothetical clinical scenario, it represents a highly relevant example of how seemingly modest changes in documentation can lead to substantial changes in perceived outcomes and performance. For example, if an institution were to implement a policy whereby all HPB procedures involving previous biliary drainage would be considered contaminated cases, the implications regarding performance assessments could be substantial. Our findings also stress the need for accurate and consistent descriptions in the surgeon's operative note, as the NSQIP surgical clinical reviewer relies on these data for appropriate coding. In addition to emphasizing the importance of closed feedback loops between the NSQIP clinical reviewer and surgeons, specific vocabulary to indicate wound classification and surgical findings should be established. As we continue to evolve systems to better assess ourselves and our institutions, it is imperative that we standardize definitions and understand the implications of our documentation.

In spite of the advantages of using a large national database, this is nonetheless a retrospective study with inherent limitations. Notably, using Current Procedural Terminology (CPT) codes as recorded in NSQIP, we were unable to adjust for the impact of laparoscopic versus open approach for most HPB procedures.¹⁸ Equally importantly, while we are confident that our logistic regression-based risk adjustment models provide robust O/E ratio

estimates, we were unable to incorporate recently implemented practices based on institutional stratification and real-time risk adjustment using hierarchical modelling, owing to the lack of hospital and surgeon-specific data in the NSQIP participant user file. Similarly, as NSQIP does not mandate the reporting of secondary procedure codes, it is possible that some patients included in the isolated liver resection group may have had a concomitant biliary/bowel procedure that was not captured, although the observed rates of SSI for each group suggest that this was a relatively rare occurrence if so. Lastly, our results are likely confounded by the fact that for more critically ill patients, operative reports may include more detailed descriptions of operative findings, possibly leading to these cases being up-coded as contaminated more often.

Overall, the findings of this study stress the need for accurate wound classification reporting, particularly as publicly available quality metrics become mandatory. We encourage work to standardize and validate reporting of wound classification as well as other important variables and outcomes. Furthermore, programmes to identify institutional outliers with respect to coding discrepancies could be developed with the goal of establishing targeted quality improvement projects. Finally, as quality improvement programmes such as NSQIP continue to introduce more procedure-specific risk models, such changes should prove more helpful for assessing quality than current summary O/E ratios.

Source of funding

This project was funded using department monies. The authors have no relevant conflicts of interest.

Conflicts of interest

None declared.

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